THE FEASIBILITY OF BIOMONITORING IN MARYLAND:

A WHITE PAPER

Prepared for the April 1, 2011 Maryland State Conference on The Feasibility of Biomonitoring

In Partial Fulfillment of Chapter 394 of the Laws of Maryland

Introduction

HB 181, enacted in 2010 as Chapter 394, directed the Maryland Department of Health and Mental Hygiene (DHMH), in consultation with the Maryland Department of the Environment (MDE), to study the feasibility of establishing a biomonitoring program in the State to monitor the presence and concentration of designated chemicals in residents of Maryland. The report, which is to be delivered on or before June 30, 2011, is specifically to:

(1) Examine biomonitoring studies conducted by the federal government, in other states, and in other countries;
(2) Examine legislative efforts in other states to establish biomonitoring programs;
(3) Consider studies on the effectiveness of biomonitoring programs and the impact of those programs on health outcomes and health care costs;
(4) Make recommendations regarding the chemicals that would be most beneficial to include in a biomonitoring program in this State; and
(5) Make recommendations on the structure of a biomonitoring program for the State, if the Department of Health and Mental Hygiene finds that a biomonitoring program would be feasible.

This white paper is part of the DHMH/MDE process for fulfillment of Chapter 394. It is intended to raise a number of questions that have been developed during the review of state, national, and international efforts on biomonitoring, and to offer alternative answers to those questions as part of public deliberation on the feasibility of biomonitoring. The white paper is intended to help shape some of the discussion around biomonitoring and provoke a discussion that can be captured and distilled in the final report to the General Assembly. The white paper does NOT seek to answer these questions at this time; nor does it purport to reflect the State's position on any aspect of biomonitoring. Rather, its function is to raise questions and elaborate some of the alternatives and issues, in a manner that raises the visibility and public discourse on this important topic.

Background

Definitions

Any discussion of biomonitoring must start with a definition. In this white paper, biomonitoring means a method of assessing human exposure to chemicals by measuring the chemicals or their

metabolites in some biological specimen such as blood, saliva, urine, or tissue. The chemicals could be pesticides, chemicals in consumer products or foods, naturally occurring chemicals in drinking water, or any other chemicals of interest.

Design of Biomonitoring Programs

There are a couple of different models for biomonitoring programs, depending on the purpose of the program. These include:

- Biomonitoring for general population exposure – One purpose for biomonitoring is to assess the concentration of specific chemicals in the general population. The best example of this is the National Health and Nutrition Examination Survey (NHANES), which looks at a broad range of chemicals in a cross-section of the population.
- Biomonitoring of specific populations – Biomonitoring can focus on specific populations. The National Children's Study aims to increase understanding of the role various environmental factors have on health and disease of children. Some biomonitoring projects focus on occupationally exposed populations (for example, pesticide exposures in agricultural workers).
- Biomonitoring in response to specific events – In some instances there could be specific events (a chemical accident, for example, or a program of some type that could potentially involve chemical exposures) in which a group of people involved in the event would be monitored for possible exposures or health consequences. Some of this monitoring might look for evidence of damage caused by exposure, such as changes in cellular DNA.

Current Biomonitoring Activities in Maryland, Other States, Nationally, and Internationally

Maryland is not the only state to consider biomonitoring. California's Environmental Contaminant Biomonitoring Program (CECBP) establishes a state-wide survey to measure chemical levels in blood and urine of California residents in order to determine average chemical levels. A distinctive feature of CECBP is the legislative requirement that biomonitoring results are returned to study participants who request them, even though the health implications may be uncertain or unknown. The Healthy Minnesotans Biomonitoring Program, enacted in 2007, has implemented four pilot projects in Minnesota, and is now doing a follow-up study of perflourochemicals and developing a state biomonitoring strategic plan.

Nationally, the largest biomonitoring program is the National Report on Human Exposure to Environmental Chemicals, conducted every 2 years by the U.S. Centers for Disease Control and Prevention (CDC) as a part of the National Health and Nutrition Examination Survey (NHANES). The Fourth Report (2009), based on biomonitoring of blood and urine from 2,400 people across the country, includes comprehensive data on 212 chemicals (including 75 new chemicals that had not been recorded in earlier editions).

The other large national biomonitoring program is the National Children's Study. A collaboration of the CDC and the National Institutes of Health (NIH), this study will examine the effects of various environmental influences on the health and development of 100,000 children across the country, following them from before birth to age 21. The study will consider several

issues such as natural and man-made environmental factors, biological and chemicals factors, physical surroundings, social factors, behavioral influences and outcomes, genetics, cultural and family influences and differences and geographic locations. Scientists will analyze samples of blood, breast milk and urine from 525 pregnant mothers and their infants after birth for more than 100 environmental chemicals and nutritional indicators. Sample collection began in summer 2009.

It should also be noted that biomonitoring programs in the occupational setting have been taking place for years. This setting is particularly important because some of the highest exposures to many chemicals occur in the workplace. Biomonitoring programs for benzene, lead, and many other chemicals were first worked out and implemented in the workplace, and the ability to distinguish between occupational and environmental exposures to chemicals is one of the challenges of biomonitoring programs.

Legislative Considerations

The National Conference of State Legislatures (NCSL) recently summarized state activities in biomonitoring (*Biomonitoring: A Best Practices Report for State Legislators*, NCSL, Washington, DC: May, 2010). In addition to summarizing many of the legislative initiatives around the country, the NCSL report describes some of the considerations for legislatures when evaluating biomonitoring proposals: (1) Program design and focus; (2) Protocols for data collection and use; (3) Community participation and outreach; (4) Partnerships with outside agencies and organizations; and (5) Determining how to leverage existing resources and strengthen needed laboratory infrastructure.

Biomonitoring Capacity within Maryland

Biomonitoring requires a sophisticated infrastructure to collect, transport, store, analyze, and report on chemicals in a variety of biologic samples including urine, saliva, blood, hair, nails, or other tissue. The entire process requires not only expensive and sophisticated laboratory equipment, but an entire process to ensure sample integrity from collection to analysis to reporting, along with quality assurance, quality control, laboratory proficiency testing, standardization, and continuous assessment of laboratory performance. Maryland's public health laboratory has received federal funding through various cooperative agreements from the CDC and the U.S. Food and Drug Administration (FDA) to develop and maintain laboratory infrastructure, and preparedness and response capability by purchasing new state-of-the-art instruments; promote staff training; develop new or modifying existing test methods; and participate in analyzing proficiency test samples to determine laboratory competency.

Since 2002, the Maryland's State public health laboratory has had the capacity to participate in human biomonitoring studies analyzing urine and blood specimens for different classes of pesticides, toxic metals, nerve agents, cyanide, toxic industrial compounds, and radionuclides, and has maintained CLIA certification for this purpose. The laboratory utilizes highly trained scientists and state-of-the-art instrumentation to routinely analyze urine and blood specimens from private and emergency room physicians at area hospitals, as well as testing for special investigations.

There are many other potential laboratory resources that could potentially play a role in biomonitoring, including resources within academic institutions, Federal and military institutions, and the private sector. All of the considerations that apply to state laboratory facilities identified earlier in this section would also apply to these facilities.

Potential Benefits and Effectiveness of a Biomonitoring Program

The National Research Council Report, *Human Biomonitoring for Environmental Chemicals* (National Research Council, National Academies Press, Washington, DC: 2006) categorized biomarkers of exposure, based on how much was known about the relationship between the biomarker, external dose, internal dose, and biological effects, as well as whether the methods of sampling and analysis were well developed. The report's findings are important because they identify questions that need to be addressed in the development of any proposed biomonitoring program:

- There is a need for a consistent rationale for selecting chemicals for study based on exposure and public-health concerns.
- Epidemiologic, toxicologic, and exposure-assessment studies have not adequately incorporated biomonitoring for interpretation of health risks at the individual, community, and population levels.
- Effective communication of results is among the biggest challenges to the future of biomonitoring.
- Biomonitoring research presents a number of bioethical concerns about informed consent and the interpretation of results. Much of biomonitoring research is conducted with anonymized samples that limit the communication of results and potential followup with study subjects.

Issues in Biomonitoring in Maryland

Technical Issues

There are many technical issues to be considered in designing a biomonitoring program for Maryland. These will be discussed at length in the final report to the General Assembly, but some of them include:

- What are the purposes of the biomonitoring program?
- Which chemicals would be monitored, in whom, and why?
- How long should specimens be stored, and what should the process be to go back and re-analyze the specimens, or to analyze for something new? Should this be allowed at all? Should participants give a general consent, or should they have to be re-contacted for new permission whenever there is a request to conduct a new analysis?
- What are appropriate comparisons for the chemical that are detected? Should comparisons be made only with other participants, or should there be comparisons with national population samples, or perhaps convenience samples from laboratories?

- What should participants be told about their results? How should that communication occur? What should participants and/or their health care providers be told regarding chemical substances detected for which there are no clear health outcomes?
- What should the public at large be told about the results? How should they be reported? What data should be available for researchers?

Interpretation and Communication of Results

As already mentioned in this paper, biomonitoring results can be interpreted with respect to an individual participant, with respect to a group, or with respect to the entire population. The audience that will be receiving, interpreting, and potentially basing decisions upon the results will have needs and expectations that cannot necessarily be predicted. Additionally, members of any audience will have varying perspectives and degrees of scientific understanding. Attention to these audience-related factors during development of the communication plan should improve the success of a biomonitoring program.

Some of the considerations in presenting results to individuals include:

- What is known about the substance and its health effects? If there is information on the health effects, is there anything that can be done to decrease the risk associated with exposure? Can exposure or dose be reduced by either active treatment or action on the part of the individual, or by avoidance of future exposures?
- If there is little known about the potential health effects of certain chemicals, what (if anything) should participants be told about their individual results? Should they know whether they are higher than, lower than, or similar to other participants or some other reference group? Is it possible for them to avoid future exposure?
- What should health care providers be told about the results? Should they be directly informed, or informed through their patients? Should the communication with health care providers be different than that with the participants?

Legal and Ethical Issues

There is a substantial amount written about legal and ethical issues in biomonitoring. Some of the ethical issues are discussed above in the sections on technical issues, and interpretation and communication of results. Some of the other questions that can be raised when discussing biomonitoring include:

- Confidentiality of results. Are these results subject to the Public Information Act or other required disclosure? If any testing involves genetic factors, who has access to that information?
- What about tests for substances for which the participants might want to have further testing or treatment? Who would cover the costs of such additional testing or treatment? What about any potential harm as a result of participation? Who is responsible for compensating participants if they are harmed?

- Does the state assume any ethical responsibility if biomonitoring shows that a particular group has unusual exposure to a substance, even if there is little known about the health implications of the exposure?

Resource Issues

Biomonitoring can be very expensive. Costs include laboratory instruments; sample collection, processing, and storage; communications; data analysis; personnel; and many other components. It is possible to reduce some of these costs, but even pilot programs can be quite expensive.